

**INTERNATIONAL PRELIMINARY EXAMINATION REPORT**  
(PCT Article 36 and Rule 70)



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| Applicant's or agent's file reference<br>57768 WO 003  | <b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416) |  |
| International application No.<br>PCT/US 03/25502   | International filing date (day/month/year)<br>13.08.2003   | Priority date (day/month/year)<br>16.09.2002 |
| International Patent Classification (IPC) or both national classification and IPC<br>A61M15/00 |  |  |
| Applicant<br>3M INNOVATIVE PROPERTIES COMPANY et al.   |  |  |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
- ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

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| Date of submission of the demand<br><br>26.01.2004  | Date of completion of this report<br><br>01.10.2004  |
| Name and mailing address of the international preliminary examining authority:<br><br> European Patent Office<br>D-80298 Munich<br>Tel. +49 89 2399 - 0 Tx: 523656 epmu d<br>Fax: +49 89 2399 - 4465 | Authorized Officer<br><br>Bevilacqua, V<br><br>Telephone No. +49 89 2399-7983<br><br> |

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/US 03/25502

**I. Basis of the report**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

**Description, Pages**

1-12 as originally filed

**Claims, Numbers**

1-19 as originally filed

**Drawings, Sheets**

1/3-3/3 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. **PCT/US 03/25502**

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

|                               |             |      |
|-------------------------------|-------------|------|
| Novelty (N)                   | Yes: Claims | 1,4  |
|                               | No: Claims  |      |
| Inventive step (IS)           | Yes: Claims |      |
|                               | No: Claims  | 1,4  |
| Industrial applicability (IA) | Yes: Claims | 1-19 |
|                               | No: Claims  |      |

2. Citations and explanations

**see separate sheet**

**Re Item V**

**Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1.  
State of the art**

Reference is made to the following documents:

D1:WO 00 29054 A (3M INNOVATIVE PROPERTIES CO) 25 May 2000 (2000-05-25)  
D2:FR-A-2 732 883 (CORREGGI RAOUL) 18 October 1996 (1996-10-18)

**2.  
Claim 1**

Document D1, which is considered to represent the most relevant state of the art, discloses (cf. figures 3-18) an adaptor which is breath actuated, this means that the user, in order to operate the mechanism has to breath, thereby applying a depressing force on the rolling element (24,26).

The subject-matter of independent claim 1 differs from this known adaptor in that the mechanism is arranged such that upon release of said mechanism by the user the valve stem of the dispensing valve will be moved automatically into its closed position.

The subject-matter of claim 1 is therefore novel (Article 33(2) PCT).

The problem to be solved by the present invention may therefore be regarded as how to allow the use of a release-to-fire container for a pressurised aerosol formulation as a conventional bress-breathe inhaler

The solution to this problem proposed in claim 1 of the present application is not considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

A mechanism arranged such that upon release of said mechanism by the user the valve stem of the dispensing valve will be moved automatically into its closed position is described in document D2 as providing the same advantages as in the present application. The skilled person would therefore regard it as a normal option to include this feature in the adaptor described in document D1 in order to solve the problem posed.

**3.**

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US03/25502

**Claim 4**

Document D1, which is considered to represent the most relevant state of the art, discloses (cf. figures 3-18) an dispenser from which the subject-matter of independent claim 4 differs in that it comprises a mechanism arranged such that upon release of said mechanism by the user the valve stem of the dispensing valve will be moved automatically into its closed position.

The subject-matter of claim 4 is therefore novel (Article 33(2) PCT).

The problem to be solved by the present invention may therefore be regarded as how to allow the use of a release-to-fire container for a pressurised aerosol formulation as a conventional bress-breathe inhaler

The solution to this problem proposed in claim 4 of the present application is not considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

A mechanism arranged such that upon release of said mechanism by the user the valve stem of the dispensing valve will be moved automatically into its closed position is described in document D2 as providing the same advantages as in the present application. The skilled person would therefore regard it as a normal option to include this feature in the adaptor described in document D1 in order to solve the problem posed.

**4.  
Conclusion**

Independent claims 1 and 4 are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (D1) being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 and D2 is not mentioned in the description, nor are these documents identified therein.